

11110 Del Rio Drive
Fairfax, VA 22030-5339
May 16, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0003

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To the FDA:

RE: DOCKET NO. 98N-1265

As a consumer of healthcare services, I strongly disapprove of the Memorandum of Understanding as published by the FDA on January 21, 1999. If this MOU goes into effect unchanged, it will infringe on my right to obtain medications upon which I rely.

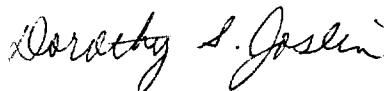
One and one-half years ago I stopped taking synthetic hormone replacement therapy (HRT) because of uncomfortable side effects and the possibility that it promotes breast cancer. I switched to natural hormones (estriol and micronized progesterone), which I obtain from a pharmacy that compounds the medication. Research has shown that patients who take estriol have the same or a lower incidence of breast cancer, compared with women who do not take HRT. Estriol may actually have a protective effect and may be used by women who have had breast cancer. My sister has had cancer. I feel safer using estriol. Also, I am taking a lower dosage of hormones now. I no longer have the unwanted side effects.

After a I took natural hormones for a year, I visited my physician for a mammography follow-up. The mammography results and clinical exam showed a positive change (lower density). My doctor told me to keep up whatever I was doing, i.e., stay on natural HRT.

As currently written, the MOU and the Compounding Section 503A of the Modernization Act restrict the rights of patients and physicians to obtain healthcare products from the providers of their choice. If the MOU is not amended, my right to use the medication of my choice, and that of other consumers and pharmacists, will be trampled upon. The MOU will infringe upon the right of the pharmacy to produce this medication. If it can produce it, I probably will be unable to obtain it, as the pharmacy is in another state.

This is not a safety issue. Do not take away our rights! **Please amend the MOU!**

Sincerely,

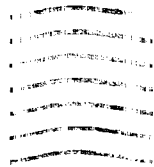


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